B' C5 cont

and, n is an integer from 0 to 6,

or its hydroquinone form, or a pharmaceutically acceptable salt thereof.--

In The Specification:

Please substitute the enclosed paper copy of the substitute Sequence Listing for the Sequence Listing set forth after page 6 of the drawings of the specification as originally filed.

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested. By the foregoing amendment, claims 1-13 and 16-28 have been amended to clarify that inhibitor compositions are being claimed. Support for this amendment to claims 1-14 and 16-28 may be found on page 8 of the specification as filed, and throughout the specification, where it is clear from the phrase "NF-κB inhibitors comprising as an active ingredient a benzoquinone derivative..." that a composition is intended. New claims 38-41 have been added. Support for new claims 38-41 may be found, at the very least, in claims 1, 14, 16 and 29 as originally filed and throughout the specification as filed. No new matter has been added by the present amendment.

Rejection of Claims 1-37 Under 35 U.S.C. § 112, First Paragraph

Claims 1-37 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner purports that one of skill in the art would not be able to determine what the scope of "optionally substituted" is. Applicants respectfully disagree because it is clear from the specification that the scope of "optionally substituted" is defined. For example, the "optionally substituted" substituents of claims 6, 21 and 34 are defined on page 13, line 25, to page 16, line 2. The "optionally substituted" substituents of claims 7, 22 and 35 are defined on page 16, lines 3 to 34. Finally, the "optionally substituted" substituents of claims 8, 23 and 36 are defined on page 16, line 35, to page 17, line 14. Furthermore, the claimed production process is described on page 24, line 24, to page 34, line 33, of the specification as filed. Thus, it would be clear to one of skill in the art who read the specification what the scope of the phrase "optionally substituted" is, and it would not take any experimentation for one of skill in the art to practice the present invention (since there would be no guessing as to what the groups of the present invention can be optionally substituted with or how the compounds are produced).

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 11-14 and 29 Under 35 U.S.C. § 112, First Paragraph

Claims 11-14 and 29 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing non-enabled subject matter. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Claims 11-14 and 29 are drawn to an NF-κB inhibitor composition which is a preventive or therapeutic agent for inflammatory diseases, for autoimmune diseases, for viral diseases, for diseases caused by the activation of NF-κB, and for diseases caused by the excessive production of TNF-α, respectively. NF-κB is activated by binding of inflammatory cytokines to their receptors. The activated NF-κB binds to the expression control regions of the genes for iNOS and TNF-α, which are inflammatory proteins, and enhances the expression of these proteins which results in severe inflammation. Therefore, inhibition of NF-κB results in the prevention of inflammatory diseases, autoimmune diseases, viral diseases, diseases caused by the activation of NF-κB, and diseases caused by the excessive production of TNF-α. Furthermore, inhibiting NF-κB would be useful for treating these diseases, since such use would result in a reduction of inflammation. As can be seen in Experiments 2 and 3 (pages 105-108) of the specification as filed, the compounds of the present invention are capable of inhibiting NF-κB activity, and thus would be useful in a composition for preventing and treating the claimed disorders. Thus, the claims are enabled by the specification.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 1-37 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-37 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. For at least all of the reasons set forth below, it is believed withdrawal of this rejection is in order.

The Examiner purports that claim 1 is indefinite because the word "comprising" is open-ended and does not exclude additional, unrecited elements. Applicants disagree. Claim 1 reads "An NF-κB inhibitor composition comprising as an active ingredient ..." Thus, the inhibitor composition can comprise ingredients other than the claimed compound, but the active ingredient of the inhibitor composition is the claimed compound. Thus, it is believed that the claims are not indefinite and this rejection should be withdrawn.

The Examiner also purports that claim 16 is a substantial duplicate of claim 1, and that claim 29 is a substantial duplicate of claim 16. Applicants disagree. Claim 1 is drawn to an NF-κB inhibitor composition comprising the compound of the present invention. Claim 16 is drawn to an TNF-α production inhibitor composition comprising the compound of the present invention. Claim 29 is drawn to an agent for preventing or treating diseases caused by the excessive production of TNF-α. Thus, the claims are drawn to different inventions and are not duplicates of one another.

In light of these remarks, applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 1-37 Under 35 U.S.C. § 103(a)

Claims 1-37 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Nunokawa et al, EP 0 864 648. Applicants note that the publication date of this European Patent was September 16, 1998, which was after the priority date of the present application (March 20, 1998). Applicants will at a later time overcome this prior art by submitting a translation of the priority document.

Rejection of Claims 1-37 Under 35 U.S.C. § 103(a)

Claims 1-37 have been rejected under 35 U.S.C. § 103(a) for purportedly being anticipated by Suzuki et al, *Chem. Pharm. Bull. 41(1)*:139-144 (1996). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Suzuki et al disclose that the compounds disclosed therein are inhibitors of platelet aggregation. The present invention claims a NF-κB inhibitor composition comprising the compounds of the present invention. There is no indication or suggestion in Suzuki et al that the compounds disclosed therein would be useful in a composition for inhibiting NF-κB. Furthermore, Suzuki et al does not disclose or suggest any of the compounds of claims 15 and 30-37. Thus, Suzuki et al does not disclose or suggest the present invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Dawn M. Gardner
Registration No. 44,118

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: November 2, 2000